PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference ONF-5915PCT	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2006/301759	International filing date *(day/month/year)* 02 February 2006 (02.02.2006)	Priority date *(day/month/year)* 03 February 2005 (03.02.2005)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYORIN PHARMACEUTICAL CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

   - [x] Box No. I — Basis of the report
   - [ ] Box No. II — Priority
   - [ ] Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV — Lack of unity of invention
   - [x] Box No. V — Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI — Certain documents cited
   - [ ] Box No. VII — Certain defects in the international application
   - [ ] Box No. VIII — Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 07 August 2007 (07.08.2007)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	Authorized officer Masashi Honda e-mail: pt08.pct@wipo.int

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

Date of mailing *(day/month/year)*	16.05.2006
Applicant's or agent's file reference: ONF-5915PCT	**FOR FURTHER ACTION** See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2006/301759	02.02.2006	03.02.2005

International Patent Classification (IPC) or both national classification and IPC

A61K31/4164, A61K9/70, A61K47/06, A61K47/10, A61K47/12, A61K47/14, A61K47/16, A61K47/22, A61K47/32, A61K47/46,

Applicant

KYORIN PHARMACEUTICAL CO., LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☐ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP	Date of completion of this opinion	Authorized officer
Facsimile No.		Telephone No.

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2006/301759

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

   ☒ the international application in the language in which it was filed

   ☐ the translation of the international application into _____ , which is the language of a translation furnished for the purposes of international search (Rule 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

   a. type of material

      ☐ a sequence listing

      ☐ table(s) related to the sequence listing

   b. format of material

      ☐ on paper

      ☐ in electronic form

   c. time of filing/furnishing

      ☐ contained in the international application as filed

      ☐ filed together with the international application in electronic form

      ☐ furnished subsequently to this Authority for the purposes of search

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2006/301759

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-19	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations:

Document 1: JP 7-215943 A (Kyorin Pharmaceutical Co., Ltd.), 15 August 1995

Document 2: WO 2000/064435 A1 (Lead Chemical Co., Ltd.), 2 November 2000

Document 3: JP 10-152434 A (Nitto Denko Corp.), 9 June 1998

Document 4: WO 95/031190 A1 (Hisamitsu Pharmaceutical Co., Inc.), 23 November 1995

Document 5: JP 2001-039873 A (Nichiban Co., Ltd.), 13 February 2001

Document 6: JP 6-145052 A (Hisamitsu Pharmaceutical Co., Inc.), 24 May 1994

Document 7: JP 4-266821 A (Lead Chemical Co., Ltd.), 22 September 1992

Document 8: JP 4-273818 A (Kissei Pharmaceutical Co., Ltd.), 30 September 1992

Document 1 states that imidafenacin is useful as a therapeutic drug for the treatment of frequent urination, urinary incontinence, and the like, but makes no disclosure pertaining to a transdermal absorption-type preparation.

Box No. V **Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

However, oral administration of a drug to elderly or bedridden patients is a known problem in the field of therapeutic drugs for the treatment of frequent urination and urinary incontinence, and as noted in documents 2 to 8, the need for a transdermal absorption-type preparation which is easily administered, is long-lasting, and has few side effects is known in the art. Thus, a person skilled in the art could easily conceive of forming a transdermal absorption-type preparation of imidafenacin.

Further, when doing so, optimizing features such as the active ingredient content and the size of the preparation is merely a process fittingly carried out by a person skilled in the art. Tackifiers such as a styrene-isoprene-styrene block copolymer, amphipathic solubilizing agents such as N-methyl-2-pyrrolidone, transdermal permeability enhancers such as triacetin, and oxidizers such as dibutyl hydroxytoluene are known components of a transdermal absorption-type preparation, as disclosed in documents 2 to 8, for example. Thus, using an appropriate combination of the various components is nothing more than the normal exercise of the faculties of a person skilled in the art.

Moreover, no exceptional effect is deemed to result from the above feature.

Accordingly, the inventions set forth in claims 1 to 19 do not involve an inventive step in the light of documents 1 to 8.

WRITTEN OPINION OF THE
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Supplemental Box

In case **the space in any of the preceding boxes is not sufficient.**

Continuation of: IPC

A61P11/00, A61P11/06, A61P13/02